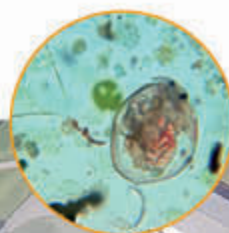
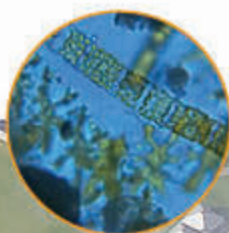


CATHELCO LTD BALLAST WATER MANAGEMENT SYSTEM

PART 4 ANNEX 1c NIOZ Quality Management Plan

Author: NIOZ

Please note: the following pages containing the NIOZ quality management plan. The page numbering runs from 1 to 15.



Quality Management Plan

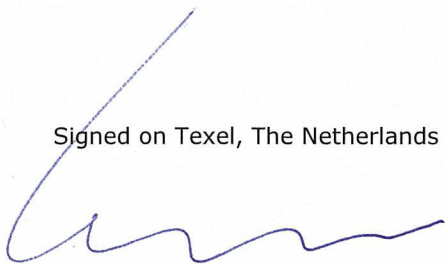
L. Peperzak

NIOZ Ballast Water Report 2012-9

NIOZ Royal Netherlands Institute for Sea Research

Quality Management Plan (QMP)

Signed on Texel, The Netherlands on: 29 August 2013

A handwritten signature in blue ink, consisting of a large, sweeping initial 'L' followed by several smaller, connected loops and a final horizontal stroke.

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TABLE OF CONTENTS

1	INTRODUCTION	7
2	QUALITY SYSTEM MANAGEMENT AND ORGANISATION	8
3	QUALITY SYSTEM COMPONENTS	9
4	PERSONNEL QUALIFICATIONS AND TRAINING	10
5	PROCUREMENT OF ITEMS AND ACTIVITIES	10
6	DOCUMENTS AND RECORDS	10
7	COMPUTER HARDWARE AND SOFTWARE	11
8	PLANNING	11
9	IMPLEMENTATION OF WORK PROCESSES	11
10	ASSESSMENT AND RESPONSE	12
11	QUALITY IMPROVEMENT	12

1 INTRODUCTION

The NIOZ Ballast Water Treatment System (BWTS) test facility is part of the department of Biological Oceanography of the Royal Netherlands Institute for Sea Research (NIOZ). NIOZ is an institute liaised to the Netherlands Organization for Scientific Research (NWO). The mission of NIOZ is to gain and communicate scientific knowledge on coastal seas and oceans for a better understanding of the system and sustainability of our planet, to manage the national facilities for sea research and to support research and education in the Netherlands and in Europe.

NIOZ is an independent academic research institute participating in numerous international research projects in coastal seas and the oceans. In addition, time series of physical, chemical and biological data from the Wadden Sea area are maintained in order to study long-term changes in the ecology of this UNESCO World heritage site. In this context the research on the efficacy of Ballast Water Treatment Systems (BWTSs) and related environmental questions fits within the NIOZ work field. NIOZ continues to build on its years of experience: since 2007 NIOZ has tested nine BWTSs (Table 1).

Table 1. Ballast Water Treatment Systems tested at NIOZ.

Year	Company	System
2007	Hamann	SEDNA
2008	EcoChlor	EcoChlor
2008	Hyde Marine	Hyde Guardian
2009	Mahle	Ocean Protection System
2009	Severn Trent De Nora	BalPure STDN
2010	Aquaworx	AquaTricomb
2010	Erma-First ESK SA	ErmaFirst
2011	Hamworthy/Wärtsilä	Aquarius-EC
2012	Hamworthy/Wärtsilä	Aquarius-UV

NIOZ works constantly on improving its methods and technologies for the accurate and precise enumeration of aquatic organisms and the measurement of their vitality and viability. These methods are compared with other organisations and test facilities in workshops and within the global network of BWTS test sites GloBal TestNet, of which NIOZ is a member. On a European level NIOZ is the lead beneficiary of the North Sea Ballast Water Opportunity project. It is policy of the institute to communicate scientific results as much as possible through international peer reviewed publications.

The NIOZ BWTS test facility not only performs land-based G8 or G9 tests. It is also equipped for laboratory tests to investigate the principles and efficiency of new technologies as well as for bench-scale tests to examine prototypes and components of BWTSs. In addition, the test facility is able to analyse and evaluate samples from other test facilities, from ship-board tests and other ballast water related activities. This evaluation may range from compliance checking with IMO standards to advanced statistical analyses. In co-operation with IMARES (Den Helder, The Netherlands) and Go-Consult it also offers a one-stop shop for complete G8 or G9 type approval, including toxicity testing, ship-board tests and dossier formation. In all activities the NIOZ test facility strives to achieve highly accurate and precise results.

This Quality Management Plan (QMP) describes the organisation of the NIOZ quality system. This consists of the quality system management and organisation, the quality system components, personnel qualifications and training, procurement of items and activities, documents and records, computer hardware and software, planning, implementation of work processes, assessment and response and, finally, quality improvement.

2 QUALITY SYSTEM MANAGEMENT AND ORGANISATION

The quality system of the NIOZ is devoted to the reliable testing of BWT systems. This means that accurate and precise measurements of the test ballast water and the treated water, including the experimental control water, need to be assured. Openness of experimental and measurement protocols, quality control, data and data analysis should lead to a high fidelity in the conclusions reached during G8/9 tests of BWTS performance and other relevant research activities. NIOZ is an IMO recognised test institute and is certified by Lloyd's Register.

The project leader of ballast water research is dr. Louis Peperzak. He is responsible for the proper functioning of the test facility and for carrying out BWTS tests, laboratory analyses, production of Standard Operating Procedures (SOPs), new methods in ballast water research (treatment, enumeration, vitality/viability measurements, compliance monitoring) and the support of all students that are involved in this research. In cooperation with members of the ballast water team he analyses the BWTSs test results and writes the G8/G9 reports as first author.

Co-project leader is dr. Jan Boon. He manages the overall Ballast Water Project at NIOZ, especially in relation to the North Sea Ballast Water Opportunity (NSBWO) project of the European Union of which the NIOZ is the lead beneficiary. He is also responsible for the external relations of the Ballast Water project. Because of his experience in chemical quality assurance programs, Dr. Boon also acts as the quality manager. He is responsible for the QMP and will evaluate all QA/QC activities of BWTS tests. He is co-author of the G8/G9 reports.

Both project leaders are assisted by Mrs. Dörte Poszig M.Sc. (general management), Mr. Marcel van der Linden (financial management) and Mrs. Marieke Holthuisen-Vloemans (external communication).

Sampling, sample analyses and first data analyses are carried out by Mrs. Josje Snoek, Mrs. Eveline Garritsen, Mrs. Eva Immler, Mr. Dennis Mosk and Mr. Alex Blin. Mrs. Eva Immler is responsible for the correct operation of the first NIOZ test installation on the Pelagia quay and for correct sampling, sample handling and storage. Mr. Dennis Mosk is responsible for the correct operation of the NIOZ test installation on the Navicula quay and for correct sampling, sample handling and storage.

The operation and maintenance of both NIOZ test installations is contracted to Mr. A. Smit of Smittech (Den Hoorn, The Netherlands) and Mr. J. Witte (Witte Klusbedrijf, Den Burg, The Netherlands)

The NIOZ ballast water team advisory committee consists of prof. Dr. Hein de Baar (chemistry), Dr. J. van Bleijswijck (molecular biology), Dr. Corina Brussaard (microbial ecology) and Dr. Klaas Timmermans (head of the department of Biological Oceanography at NIOZ).

The Quality Management Plan (QMP) and Quality Assurance Project Plan (QAPP) will be reviewed annually by an external independent consultant. In 2012 this was performed by dr. S. Kools of Grontmij (The Netherlands). In addition, by request of the BSH a review on QA/QC aspects was performed by dr. A. Cangelosi of GSI (USA). Comments of both parties have been used in the present project plan that includes both QMP and QAPP.

3 QUALITY SYSTEM COMPONENTS

The quality system of the NIOZ BWTS test facility contains several components of which this QMP is the main document. The QMP is the joint responsibility of both project leaders of the NIOZ Ballast Water Project. The QMP forms the basis of the project's quality assurance and quality control (QA/QC).

The Quality Assurance Project Plan (QAPP) is the project-specific technical document reflecting the specifics of the NIOZ test facility, the BWTS tested, and other conditions affecting the actual design and implementation of the required experiments. The QAPP consists of general information, specific information of the test facility and the BWTS tested, test water quality, sampling and sample storing, the measurement of IMO-required variables and a general outline of the QA/QC. Variable specific QA/QC measures are contained in each individual SOP, that together form section three of the QAPP.

Notebooks are used to record data, observations and deviations from SOPs, that are made during BWTS tests as well as during laboratory analyses. All notebooks are stored in the NIOZ Ballast Water archive. In a number of cases, such as in monitoring NIOZ harbour test water temperature and salinity, and in the in-line measurement of turbidity and salinity of test water at intake, data loggers are used to store information electronically. All digital information is stored on a dedicated server that is accessible to Ballast Water project personnel only.

Specific forms are used to record data during specific routine monitoring activities. These activities include monitoring of meteorological and environmental data and equipment functioning during BWTS tests, as well as the identification and enumeration of $> 50 \mu$ organisms. All forms are stored on paper in the NIOZ Ballast Water archive or in electronic format on the Ballast Water project server.

Specific forms for sample custody are also used in case of the analyses of pathogenic bacteria or specific chemical (toxicological) analyses, which are carried out in third parties commercial laboratories.

Standard Operating Procedures or SOPs are available for each IMO variable that the test facility is obliged to measure. For abiotic variables the analysis methods stem from decades of NIOZ experience as an oceanographic institute. New methods, in particular those for biological variables, are or will be published in international peer-reviewed scientific journals.

In addition, SOPs are present for specific actions during the BWTS testing such as for adjusting the salinity of the test water, flow cytometer data analysis or the cleaning of ballast water tanks.

SOPs are numbered by year and version. Paper copies are kept in the NIOZ test facility archive. Electronic copies are stored on a dedicated server that is accessible to Ballast Water project personnel only. SOPs will be critically reviewed during the operation of the test facility as well in general annual reviews by the quality manager. SOPs relevant to the QAPP can be found in section 3 of this project plan.

The test protocol (QAPP, QMP and SOPs) are submitted before the start of the BWTS tests to the class societies that were designated by the national authorities. These are the BSH (Bundesamt fuer Seeschifffahrt und Hydrographie or Federal Maritime and Hydrographical Agency, Hamburg) for Germany and Lloyds Register (London, Rotterdam) for The Netherlands (Inspectie Leefomgeving en Transport, ILT), United Kingdom (Maritime and Coastguard Agency, MCA) and Greece. The BSH and LR are notified in advance of the BWTS test dates including the days of intake and discharge, and are invited to witness all test related activities at the NIOZ test facility. In 2012 additional oral presentations on BWTS testing at NIOZ were given to the Dutch IMO representative and ILT, the BSH and to Lloyds Register.

4 PERSONNEL QUALIFICATIONS AND TRAINING

All research personnel of the NIOZ test facility are actively involved in the development of SOPs and the QA/QC measures within these SOPs. The quality manager is responsible for the QA/QC in each SOP and he checks the proper execution of QA/QC during BWTS testing and the analysis of samples and data. The quality manager will report the acquired QA/QC information to the project leader of ballast water research who will, if necessary, instruct the personnel to adjust QA/QC measures. The quality manager will also use this information in his evaluation of the BWTS test results.

All research personnel of the NIOZ test facility is trained in such a way that at least two staff members are able to perform a specific sampling or analysis. This should prevent personal bias in sample and data analysis. In addition, this procedure ensures that in case of unexpected absence sampling or sample analysis can still be carried out by trained personnel.

In case of non-automated sample analysis, the microscopic identification and enumeration of planktonic organisms the research personnel is trained in groups of three. At the beginning of each year NIOZ test water is analysed by all three staff until the difference in individual plankton concentrations is < 10%. Furthermore, in the case of > 50 µm organisms, the correct execution of sample and analysis procedures and identification and enumeration of the organisms is audited by annually by an external independent consultant. In 2012 this was performed by Mr. F. Fuhr of KiTe Aquatic Resources Consulting (The Netherlands).

Additional training of staff members takes place on-the-job during inter-comparison workshops of the ballast water test team in cooperation with the planktonlab of the department of biological oceanography of NIOZ. One such workshop was the comparison of flow cytometers held in January 2012. Furthermore, a statistics course is planned for autumn-winter 2012.

5 PROCUREMENT OF ITEMS AND ACTIVITIES

The BWTS test facility is part of the NIOZ research institute and is required to use the NIOZ facilities for procuring items and services that include all sampling and laboratory equipment and chemicals. The financial management assistant to the test facility ensures that all procedures are as required by internal NIOZ rules and by Dutch law. Material and equipment for the test installations is procured by Mr. A. Smit of Smittech (Den Hoorn, The Netherlands).

In all cases of procurement the quality, costs and supplier reputation are evaluated by research staff or Mr. A. Smit in collaboration with the project leader of Ballast Water research or, in his absence, the quality manager.

6 DOCUMENTS AND RECORDS

Documents related to the NIOZ test facility and BWTS testing include: legal and financial contracts, BWTS-specific project plans (including QAPP, QMP, SOPs), North Sea Ballast Water Opportunity (NSBWO) documents, notebooks, data and custody forms, student reports, internal reports on for instance inter-comparison workshops and scientific publications.

Legal and financial contracts are archived as required by NIOZ under the responsibility of the financial management assistant and the overall project manager. North Sea Ballast Water Opportunity (NSBWO) documents are maintained by the general and financial management assistants or by the project leaders. Notebooks, data and custody forms will be archived for at least five years by the project leader of ballast water research. BWTS-specific

project plans (including QAPP, QMP, SOPs), student reports, internal reports and scientific publications are also archived by the project leader of ballast water research.

Reports on new technologies as well as for bench-scale tests to examine prototypes and components of BWTs are numbered sequentially as "NIOZ Ballast Water Report yyyy-1,2,...".

The generic BWTs-specific project plan (including QAPP, QMP, SOPs) as well as the G8 and G9 reports will also be numbered sequentially as NIOZ Ballast Water Reports. These documents will be made publically available on the NIOZ web site.

7 COMPUTER HARDWARE AND SOFTWARE

The computer hardware that is used in the NIOZ test facility consists of lap tops and personal computers that use Windows™ based software. Both hard- and software are maintained by the NIOZ "Information and Presentation Centre" (IPC). IPC is also responsible for the security of data and other information, for instance by up-to-date virus protection and daily back-ups. The NIOZ network can only be accessed by authorised personnel and students.

In addition, all BWTs test data are stored on a dedicated network-share that is accessible only to authorised ballast water team members. This authorisation needs to be granted by both IPC and one of the project leaders of the ballast water project.

All software used by the NIOZ test facility, including Microsoft Office and dedicated software for data analysis, is legally obtained.

8 PLANNING

Manufacturers of BWTs that approach the NIOZ facility for testing of their equipment should be aware of several planning criteria.

First of all, because NIOZ uses natural test water spring and summer are the only periods of the year in which proper testing according to IMO regulations and NIOZ quality objectives can be performed. Second, as part of a research institute it is of interest to the facility that the BWTs to be tested is of a different design as previously tested BWTs.

The two project leaders of the test facility jointly decide on the admission of a BWTs for land-based testing. In case of requests for combined land-based and ship-board tests the admission will be discussed with the NIOZ partners IMARES and GoConsult. Contracts on behalf of the NIOZ will be signed by one of the NIOZ directors.

The provisional project plan and planning for testing the BWTs is made by the project leader of ballast water research. Next, the provisional project plan and planning is discussed in the ballast water team where all practical issues including those related to quality management will be dealt with.

9 IMPLEMENTATION OF WORK PROCESSES

Quality management objectives as specified in this QMP and in the QAPP and SOPs will be implemented in the work process. At the lowest level, individual members of the facility's test team are responsible for carrying out quality checks as detailed in SOPs on a daily basis. The quality manager is responsible for supervising QA/QC activities during all test and laboratory activities. The quality manager will give his feedback during each team meeting, that is scheduled at least bi-weekly during BWTs tests. On advice of the quality manager, the project leader of ballast water research gives permission in cases that quality documents need to be revised or new ones have to be made.

10 ASSESSMENT AND RESPONSE

During BWTS tests inspections may be made by inspectors of Lloyds Register or the BSH depending on the national authority that will apply for type approval at IMO.

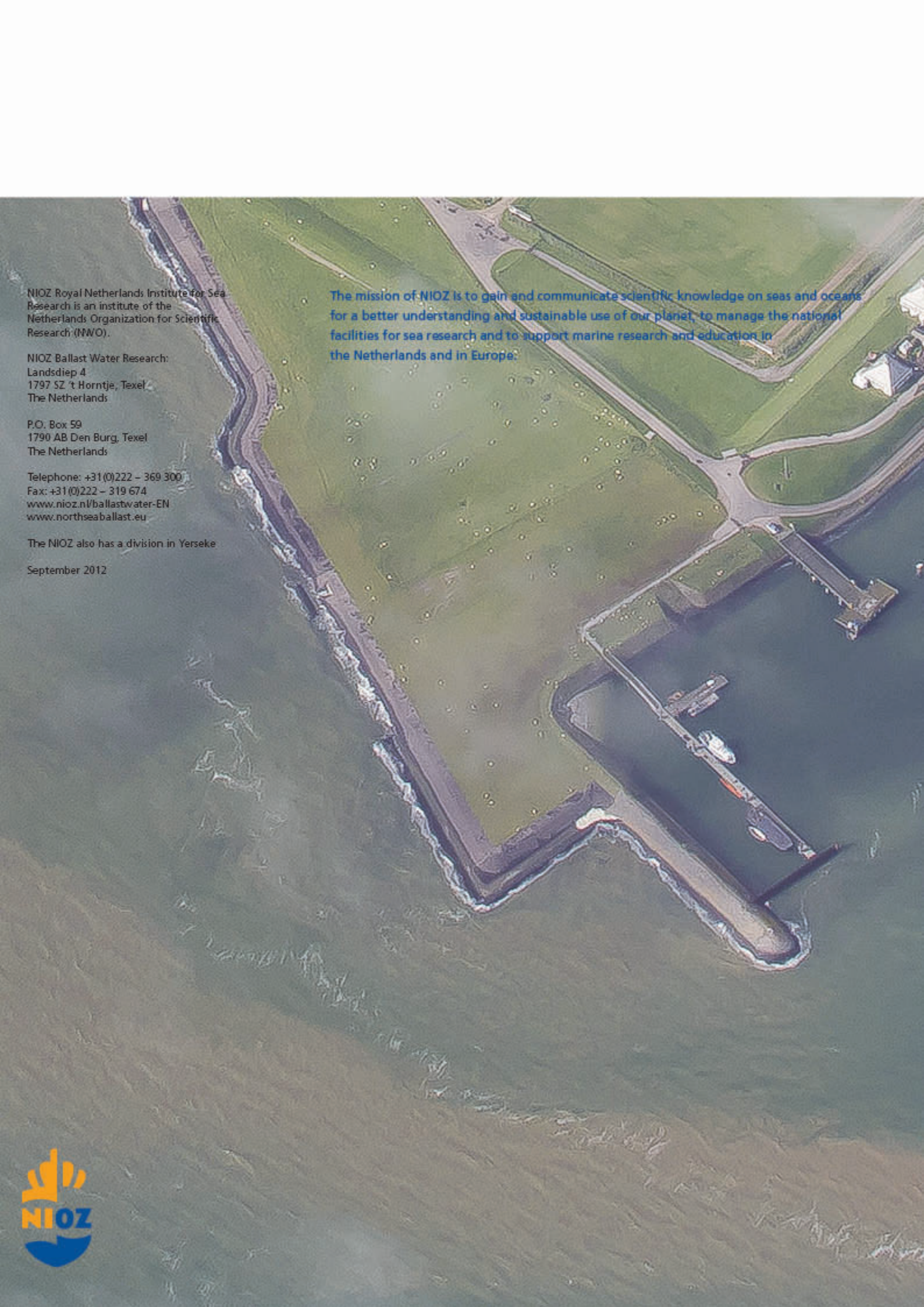
All ballast water team members are obliged to report deviations from quality standards or procedures to the quality manager. At the end of each BWTS test the quality manager will report on all deviations from the QAPP or from QA/QC measures in SOPs. The quality manager also checks the BWTS test data that are compiled by the project leader of ballast water research. The project leader of ballast water research will report any deviations in harbour test water monitoring data and intake test water data from the QAPP.

11 QUALITY IMPROVEMENT

All team members are motivated to enhance specific QA/QC measures and methods. Regular feedback between team members and the quality manager will enhance self-improvement. In addition, the NIOZ quality objectives are submitted to independent external review.

NIOZ test facility methods are compared and discussed in NSBWO workshops with other test facilities and experts in the field of ballast water research. Proficiency tests for the enumeration of aquatic organisms will improve the quality of analyses and will enhance the comparison of results between test facilities.

The NIOZ test facility invites comments to improve the quality of its test and its test data, for instance from class societies and through its membership of Global Testnet.



NIOZ Royal Netherlands Institute for Sea Research is an institute of the Netherlands Organization for Scientific Research (NWO).

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The NIOZ also has a division in Yerseke

September 2012

The mission of NIOZ is to gain and communicate scientific knowledge on seas and oceans for a better understanding and sustainable use of our planet, to manage the national facilities for sea research and to support marine research and education in the Netherlands and in Europe.



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Revision	Date	Description	Author	Checked	Approved
01	13/09/13	Revision	PH	RF	MD
00	13/09/13	Initial Issue	PH		